

Department of Pesticide Regulation

Gray Davis Governor Winston H. Hickox Secretary, California Environmental Protection Agency

MEMORANDUM

TO: Joseph P. Frank, D.Sc., Senior Toxicologist

HSM-03023

Worker Health and Safety Branch

FROM: Michael H. Dong, Ph.D., Staff Toxicologist (Specialist) [original signed by M. Dong]

Worker Health and Safety Branch

(916) 445-4263

DATE: October 24, 2003

SUBJECT: WORKER EXPOSURE FROM USE OF FIREPRO® IN WOOD PRESSURE

TREATMENT FACILITIES

Data package dated January 8, 2003, with the Tracking No. 196582, requests Worker Health and Safety (WHS) Branch reconsider the use of FirePro® for pressure treatment of wood products. FirePro (EPA Reg. No. 3008-84), manufactured by Osmose, Inc., is for use either as an interior type A high temperature fire retardant, or as a preservative to protect against wood decay fungi, wood boring insects, and termites. The product contains 25% of boric acid (by weight) and 45% of sodium tetraborate pentahydrate (STBPH) as the active ingredients (AI). WHS completed the earlier evaluation (Formoli, 2002) with a request that the registrant provide a description of the pressure treatment procedures so that staff can assess more accurately the inhalation exposure involved. There was a concern over the inhalation exposure involved because the AI in FirePro were presumed to be processed at some high pressure temperature. In response to this concern as well as to the Branch's specific request, the registrant hence submitted a user manual on the product's pressure treatment procedures. Below are the observations and explanations justifying why, at this time, the worker exposure at issue still cannot be concluded as insignificant.

Boric acid (H₃BO₃) and STBPH (Na₂B₄O₇·5H₂O) are specifically made of the element boron, which is naturally occurring and appears to be an essential nutrient to humans and many other organisms. However, neither AI is readily convertible to boron in the human body; and either can be toxic to humans in its own form when given at high enough doses. Furthermore, even though boric acid can be used as a fire retardant, its presence with potassium may cause explosion. The six sodium borate salts, of which STBPH is one, are also referred to loosely as boric acid, in that the salts can be readily converted to the acid in many biological systems. In fact, these borates are thought to be chemically and toxicologically equivalent to boric acid. A dilute water solution of boric acid is commonly used as a mild antiseptic and eyewash. The weak acid is also used in leather manufacture and cosmetics, in addition to its pesticidal role.

Boric acid is volatile at high (e.g., steam) temperature. The chemical can enter the human blood by inhalation where it can decrease the pH level with the possible side effects of respiratory, renal, or cardiovascular failure. Signs and symptoms of boric acid poisoning may include nausea, vomiting, diarrhea, abdominal cramps, erythematous lesions on skin/mucous membranes, circulatory collapse, tachycardia, convulsions, coma, and even death (Merck Index, 1996). Boric acid, as well as its borate salts, is generally known as a desiccant due to the fact that these substances can terminate the target pests by causing severe dehydration in the

Joseph P. Frank October 24, 2003 Page 2

organisms' body. Available toxicity studies showed that at high doses, boric acid induced adverse developmental, reproductive, or maternal effects in rats, mice, or rabbits (Heindel *et al.*, 1994; U.S. EPA, 1993).

In the earlier review and this reassessment, the concern is primarily with the workers' inhalation exposure from handling FirePro in the wood pressure treatment facilities. Even though the borate is not fixed to the treated lumber and thus can leach out (or diffuse further into the wood), the exposure of children or bystanders from hand-to-mouth and the kind is expected to be negligible since their dermal (hand) contact with treated interior wood is minimal, intermittent, or otherwise short-lived. The dermal contact is likewise considered to be minimal for workers adding latex or oil-based paints to the wood treated with FirePro. The dermal absorption of boric acid is sufficiently low (less than 1 or 2%), especially on an intact and healthy skin (Clarkson, 1991). In both cases, inhalation exposure is also considered to be insignificant in that boric acid and its borates are not volatile at room temperature.

The FirePro label requires handlers to wear the following personal protective equipment (PPE): goggles or face shield; coveralls over long pants and a long-sleeved shirt; chemical-resistant footwear plus socks; chemical-resistant gloves, and when cleaning the equipment, a chemical-resistant apron. These PPE requirements thus suggest that the worker exposure of main concern is from the respiratory intake of boric acid when handlers are working in the wood pressure treatment facilities. The label refers product users to the pressure treatment procedures described in the Osmose FirePro Treatment and Processing Manual (FPTPM), or to those described in the American Wood Preservers' Association Standards (AWPAS). According to the AWPAS, the wood treatment solution temperature should be approximately 200°F, whereas the FPTPM specifies that the FirePro solution temperature must not exceed 125°F. Neither user manual requires FirePro workers to wear a full- or half-face respirator in areas where the air concentration of boric acid is at or below the permissible exposure level (PEL) of 10 mg/M³.

A study was used earlier (Brodberg and Thongsinthusak, 1998) for the exposure assessment of pentachlorophenol (PCP), another AI also used as a wood preservative in pressure treatment facilities. In that trial, the PCP air levels close to the pressure treatment areas were found to be as high as 0.2 mg/M³. That high-end air level hence would yield a daily PCP intake of 10 μ g/kg [= (200 μ g/M³) x (7 M³) x (50% default inhalation absorption) x (70 kg)-¹], based on the assumption that a worker, with an average body weight of 70 kg, would inhale approximately 5 to 7 M³ of air in a pressure treatment facility during an eight-hour workday.

The product used in the above trial contained 86% (by weight) of PCP as the AI, which has a low vapor pressure of 1.1×10^{-4} mm Hg at 20° C. While the boric acid and the STBPH in FirePro together amount to a comparable 70% of the product, the MSDS (material safety data sheets) for some borate products indicate that either AI's vapor pressure is greater than PCP's by *several* orders of magnitude at room temperature. This physicochemical property alone thus suggests that the inhalation intake of boric acid can be much greater than $10 \, \mu g/kg/day$ for FirePro handlers working in a pressure treatment facility, even if a lower pressure temperature is used.

Joseph P. Frank October 24, 2003 Page 3

The daily usage of the FirePro product in a pressure treatment facility is assumed to be comparable to the daily amounts of the PCP product used in the surrogate trial facilities.

Where chemical-specific toxicity data are unavailable to establish a critical NOEL (no observed effect level), the safe dosage is set at $0.3~\mu g/kg/day$ by Branch policy (Donahue, 1996) for effects such as teratology that can take place following a single exposure. In short, a boric acid intake of well above $10~\mu g/kg/day$, as so presumed above for the FirePro workers, cannot be considered by default as insignificant. The PEL of $10~mg/M^3$ for occupational exposure, which allows a rather high intake of borates, was not set for any of the adverse reproductive, developmental, or maternal effects at issue.

Boron is present in food, water, laundry, cosmetics, pharmaceuticals, etc. The daily intake of boron from these sources has been estimated to range from 0.5 to 20 mg/day for adult humans, with an average of 3 mg/day or approximately 40 μ g/kg/day (Hunt *et al.*, 1991; Nielsen, 1991; Seiler and Sigel, 1988; WHO, 1973). And the conversion factor for borates to boron, as on the basis of their molecular weights, is greater than 5 to 1. However, these facts alone cannot be used to suggest that the natural occurrence level (NOL) is 240 μ g/kg/day (= 6 x 40 μ g/kg/day) for borates or boric acid. Metabolism of boric acid is simply thermodynamically unfavorable in *biological* systems (WHO, 1998).

At best, boron's NOL can serve only as an indication that some small amount of borate or boric acid in the human body is tolerable, based on the rather weak argument that the unmetabolized boric acid can still be considered as chemically and toxicologically related (but not equivalent) to boron. In any event, it is not quite correct to use, as in earlier assessments for some other borate products, the average NOL (e.g., 40 µg/kg/day) of boron for boric acid or borates. In those earlier assessments, the boron's NOL was referenced under the implicit assumption that a borate's toxic potency is not more than 10 times of boron's. With that assertion, the same NOL for boron could be and was used for borates since the conversion factor for borates to boron is 6:1 or greater. It is important to note that whenever in taking the natural occurrence approach, it is the average level, not the upper end of the range, that is typically used as the benchmark (i.e., the safe level) since the exposure in question is an add-on to the natural occurrence range.

Available toxicity data suggest that the critical NOEL may be well above 100 mg/kg/day in rodents (Heindel *et al.*, 1994), which may exceed the boric acid intake presumed above for FirePro workers by as much as 3 orders of magnitude. However, it is beyond the purview of this reassessment to determine whether or not the *toxicity* data on hand are acceptable and sufficient. Nor is this the proper place to use the data on hand to establish a critical NOEL for boric acid.

On the other hand, the benchmark margin of exposure (MOE) typically is 100 to account for a 10-fold safety factor for interspecies variability and another 10-fold factor for intraspecies sensitivity. In the case with FirePro, the benchmark MOE should be defaulted to 1,000 or greater in order to account for further uncertainties associated with the quality and the adequacy of the toxicity and the exposure data on hand. To reduce some of these additional uncertainties,

Joseph P. Frank October 24, 2003 Page 4

it is recommended that, as a minimum, a preliminary toxicity assessment be conducted to determine how likely the critical NOEL for boric acid is, or is not, well above 100 mg/kg/day.

In conclusion, as stated at the outset of this reassessment, **the worker exposure in question still cannot be concluded as insignificant at this time**. One possible mitigation alternative is for the registrant to submit some empirical data showing that the vapor pressures for both boric acid and STBPH, at room or preferably steam temperature, are indeed comparable to PCP's. The more convincing alternative is, however, for the registrant to provide one or more acceptable *onsite* air monitoring studies confirming the sufficiently low air levels of boric acid and STBPH, that FirePro handlers would encounter in the wood pressure treatment facilities, as so implicitly or explicitly asserted by the registrant.

A complete list of references is attached.

Attachment

cc: Tareq Formoli, WHS Joshua Johnson, WHS

References

- Brodberg RK, Thongsinthusak T, 1998. Estimation of Exposure of Persons in California to Pesticide Products That Contain Pentachlorophenol (PCP). HS-1596. Worker Health and Safety Branch, Cal/EPA Department of Pesticide Regulation.
- Clarkson TW, 1991. Inorganic and Organometal Pesticides. In: *Pesticides Studied in Man* (Hayes WJ, Jr., Laws ER, Jr., Eds.). Williams & Wilkins, Baltimore, MD, Chapter 12.
- Donahue JM, 1996. Parameters Defining Insignificant Exposure. HSM-96006. Worker Health and Safety Branch, Cal/EPA Department of Pesticide Regulation.
- Formoli TA, 2002. Request for Insignificant Exposure Assessment for FirePro, EPA Registration No. 3008-84. HSM-02043. Worker Health and Safety Branch, Cal/EPA Department of Pesticide Regulation.
- Heindel JJ, Price CJ, Schwetz BA, 1994. The Developmental Toxicity of Boric Acid in Mice, Rats, and Rabbits. *Environ Health Perspect* 102 (S7): 107-112.
- Hunt CD, Shuler TR, Mullen LM, 1991. Concentration of Boron and Other Elements in Human Foods and Personal-Care Products. *J Amer Dietetic Assoc* 91:558-568.
- Merck Index (The), 1996. Boric Acid. Merck & Co., Rahway, New Jersey, 12th Edition.
- Nielsen FH, 1991. Nutritional Requirement for Boron, Silicon, Vanadium, Nickel, and Arsenic: Current Knowledge and Speculation. *FASEB J* 5:2661-2667.
- Seiler HG, Sigel H, 1988 (Eds.). *Handbook on Toxicity of Inorganic Compounds*. Marcel Dekker, New York, Chapter 12.
- U.S. EPA (U.S. Environmental Protection Agency), 1993. *R.E.D. Facts Boric Acid.* EPA-738-F-93-006. Office of Prevention, Pesticides and Toxic Substances, Washington DC.
- WHO (World Health Organization), 1973. Trace Elements in Human Nutrition. WHO Technical Report Series 532, Geneva.
- WHO (Word Health Organization), 1998. Boron. Environmental Health Criteria 204, WHO International Programme on Chemical Safety, Geneva.